CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA
3-CHLORO-p-TOLUIDINE HCl

Chemical Code # 549, Tolerance # 50989

December 11, 2002

I. DATA GAP STATUS

Chronic toxicity, rat:	No study on file.
Chronic toxicity, dog:	No study on file.
Oncogenicity, rat:	No study on file, summary statement only.
Oncogenicity, mouse:	No study on file, summary statement only.
Reproduction, rat:	No study on file.
Teratology, rat:	No study on file.
Teratology, rabbit:	No study on file.
Gene mutation:	No data gap, no adverse effects.
Chromosome effects:	No data gap, possible adverse effect.
DNA damage:	No study on file.
Neurotoxicity:	Not required at this time.

Toxicology one-liners are attached.

All record numbers through 129195 were examined.
** indicates an acceptable study.
Bold face indicates a possible adverse effect.
File name: T021211
Prepared by J. Gee, December 11, 2002

3-Chloro-p-toluidine HCl is registered as an avicide. A memorandum dated October 8, 1996, from Karen Fletcher to John Inouye of the Pesticide Registration Branch, indicates that, based on limited exposure, the studies mandated under SB950 are not being required for this active ingredient. Therefore, no further studies are being required at this time.

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

CHRONIC TOXICITY, RAT

No study on file.

CHRONIC TOXICITY, DOG

No study on file.

ONCOGENICITY, RAT

001 045138 Statement that treatment for a "lifetime" to rats did not indicate oncogenic effect with a citation of "Anonymous, 1978. Bioassay of 3-chloro-p-toluidine for possible carcinogenicity. US Dept. of Health, Education and Welfare, NIH." Not on file.

ONCOGENICITY, MOUSE

001 045139 Statement that treatment of mice for a "lifetime" did not show evidence of oncogenicity. Citation: As for 45138 above under rat. Not on file.

REPRODUCTION, RAT

No study on file.

TERATOLOGY, RAT

No study on file.

TERATOLOGY, RABBIT

No study on file.

GENE MUTATION

** 003; 129193 "Ames/Salmonella Plate Incorporation Assay." (L. F. Stankowski, Jr., Pharmakon Research International, Inc., Waverly, PA); Lab Study No. PH 301-DW-001-90; 7/29/90 3-Chloro-p-toluidine HCl (Lot No. 892149; 97% purity), diluted in DMSO was tested with Salmonella typhimurium strains TA98, TA100, TA1535, TA1537, TA1538 with and without activation (Aroclor 1254-induced rat S9 fraction), by plate incorporation. Concentrations were 0 (DMSO), 50.0, 167, 500, 1000, 1670, 2500 ug/plate in triplicate, single trial. Cytotoxicity was noted at 1670 and 2500 ug/plate with no increase in reversion rates. No adverse effects. Acceptable. (Duncan, 5/10/94)

003 129195 "CHO/HPRT Mammalian Cell Forward Gene Mutation Assay." (L. F. Stankowski, Jr., Pharmakon Research International, Inc., Waverly, PA); Lab Study No. PH 314-DW-001-90; 8/15/90) 3-Chloro-p-toluidine HCl (Lot no. 89214, purity: 97%); diluted in DMSO, was tested with CHO-K1-BH4 cells with and w/o activation (Aroclor 1254-induced rat S9 fraction). Concentrations of test article were 0, 0 (DMSO), 5.0, 10.0, 50.0, 100, 150, 200, 250, 300, 350 and 400 mg/ml with S9, 5.0, 10.0, 50.0, 100, 500, 600, 700, 800, 900, 1000 mg/ml w/o S9, positive controls: ICR 191 (w/o S9)-0.50, 1.0 mg/ml, DMN (with S9)-100 mg/ml. A precipitate formed in

the culture medium at ≥ 500 ug/ml. Extreme toxicity was observed at ≥ 1670 ug/ml in non-activated cultures and at ≥ 500 ug/ml in activated cultures. Results: no increase in forward mutation rates; no adverse effects. Study unacceptable (no confirming trial), not upgradeable. (Duncan and Moore, 5/17/94).

CHROMOSOME EFFECTS

**** 003 129194** "In Vitro Chromosome Aberration Analysis in Chinese Hamster Ovary (CHO) Cells" (J. R. SanSebastian, Pharmakon Research International, Inc., Waverly, PA); Lab Study No. PH 320-DW-001-90; 8/8/90) 3-Chloro-p-toluidine HCl (Lot No. 892149; 97% purity), diluted in dH2O, was assayed with CHO-K1-BH4 cells with and without activation (Aroclor 1254-induced rat S9 fraction. Concentrations tested were 0 (dH2O), 25, 125, 250, 350 ug/ml in duplicate, single trial. Five-hour exposure period, 18 hour post-treatment incubation, scored 100 cells per concentration. Possible adverse effect: increase in aberrations at 250 ug/ml and 350 ug/ml with activation. Acceptable. (Duncan, 5/12/94)

DNA DAMAGE

No study on file.

NEUROTOXICITY

Not required at this time.

OTHERS:

50989 001 45142, 45143, 45144 LD_{50} for mouse oral, rat oral, rabbit dermal acute studies. No worksheet. LD_{50} value only. Page two of "item D" states that the active ingredient is a severe irritant for skin and eyes with no data. There is a table of mortality for dogs given a single oral dose ranging from 50 to 1000 mg/kg. Both animals died at 100 mg/kg and greater. (Gee, 12/11/02).

001 045140 Summary statements regarding feeding of mice for 546 days. See under Oncogenicity, rat, above for reference. Not on file.